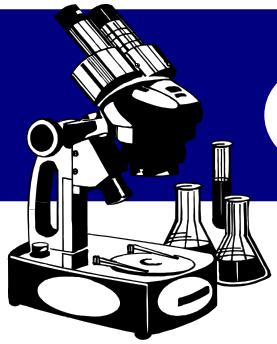

CLIA BITS

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Establishment and Verification of Performance Specifications

By Bridget Weidner, Program Manager

The new CLIA regulation at 493.1253 requires that all nonwaived test systems introduced into the laboratory on or after April 24, 2003, have establishment or verification of performance specifications performed. This includes anytime a laboratory replaces a test system or instrument, adds a new test, or changes to a different manufacturer of a test kit.

Laboratories are not required to verify or establish performance specifications for any test system used by the laboratory before April 24, 2003.

Verification of Performance Specifications

Before reporting patient test results, each laboratory that introduces an unmodified, FDA-cleared or approved test system must verify the manufacturer's performance specifications for accuracy, precision, reportable range and reference range. Laboratories may use the manufacturer's performance specifications as a guideline, but the lab is responsible for verifying the manufacturer's analytical claims prior to patient testing. This process helps to ensure that the test system, when used in your laboratory by your testing personnel for your patient population, is performing as the manufacturer intended.

Verification of accuracy may be done by:

- Testing reference materials; or
- Comparing test results against the results of a reference method; or
- Comparing split sampled results with results obtained from a method that is shown to provide clinically valid results.

Verification of precision needs to assess day-to-day, run-to-run, and within-run variation, as well as operator variance. This may be accomplished by:

- Repeat testing of known patient samples over time; or
- Testing QC material in duplicate and over time; or
- Repeat testing of calibration materials over time.

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Special points of interest:

- All nonwaived test systems introduced into the laboratory on or after April 24, 2003 must have establishment or verification of performance specifications performed.
- Records of performance specification must be retained for the period of time the laboratory uses the system but no less than two years.

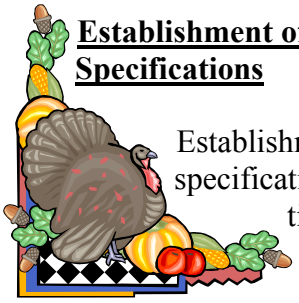
Establishment and Verification of Performance Specifications (cont)

Verification of reportable range may be accomplished by:

- Assaying low and high calibration materials or control materials; or
- Evaluating known samples of abnormal high and abnormal low values.

Verification of the reference intervals can be done over time. The laboratory may use the manufacturer's reference range, provided it is appropriate for the laboratory's patient population. If the manufacturer has not provided reference ranges appropriate for the laboratory's patient population, published reference ranges may be used. The laboratory must evaluate an appropriate number of specimens to verify the manufacturer's claims for normal values or the published reference ranges.

Laboratories may simultaneously verify multiple performance specifications by choosing appropriate samples such as repeatedly testing (precision) samples with known (accuracy) high and low values (reportable range). This testing should be performed among all operators on different days.



Establishment of Performance Specifications

Establishment of performance specifications is similar to verification of performance specifications; however, establishment of performance specifications refers to modified FDA-cleared or approved test systems, test systems not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures, Gram stain, or potassium hydroxide preparations), or test systems in which the manufacturer does not provide performance specifications. In these cases, the laboratory must, before reporting patient test results, establish each test system's performance specifications for accuracy, precision, analytical sensitivity, analytical specificity to include interfering substances, reportable range, reference range, and any other performance characteristics required for test performance. In addition, the laboratory must determine the test system's calibration procedures and control procedures based upon the performance specification.

Establishment of accuracy, precision, reportable range and reference range can be done using the same approaches that were discussed above under Verification of Performance Specifications.

Establishment of analytical sensitivity – The lab must determine the lowest concentration or amount of analyte or substance that can be measured or distinguished from a blank (minimum detection limits or how much of the analyte must be present to be measured).

Establishment of analytical specificity – The laboratory must determine the extent to which the method measures the analyte for which it is reporting results.

Establishment of interfering substances – The laboratory must document information regarding interfering substances from product information, literature or its own testing.

Establishment of calibration and control procedures –The frequency for calibration and control performance must not be less than the frequency specified in the manufacturer's instructions. When establishing the calibration and quality control frequency, consider:

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Establishment and Verification of Performance Specifications (cont)

- Test system instrument/reagent stability, including relocation.
- Frequency with which the test is performed.
- Technique dependence of the method.
- Frequency of quality control failures.
- Training, experience, and competency of technical personnel.

How many samples need to be tested in order to verify or establish performance specifications? The rule of thumb is to test 20 samples; however, this number is flexible. Your laboratory may need to test more or fewer samples depending on your specific test systems, testing volume, and other unique situations in your laboratory. This decision should be made with the help of your laboratory director. The laboratory director also should approve the results of the verification or establishment of performance specifications. Once approved, the laboratory may begin using the test system for patient testing.

Make sure you do not forget about your laboratory information system (LIS). If the LIS performs any calculations to determine a laboratory result, the calculations must be verified immediately after the LIS is programmed and prior to initial calculation of patient results. Your laboratory quality assessment plan also should ensure that the LIS programming is correct over time.

All establishment and verification activities must be documented. As always, records of performance specification must be retained for the period of time the laboratory uses the system but no less than two years.

Giving Thanks

For the hay and the corn and the
wheat that is reaped,
For the labor well done, and the
barns that are heaped,
For the sun and the dew and the
sweet honeycomb,
For the rose and the song and the harvest brought
home --
Thanksgiving! Thanksgiving!
For the trade and the skill and the
wealth in our land,
For the cunning and strength of the
workingman's hand,
For the good that our artists and
poets have taught,
For the friendship that hope and
affection have brought --
Thanksgiving! Thanksgiving!
For the homes that with purest
affection are blest,
For the season of plenty and well-deserved rest,
For our country extending from sea unto sea;
The land that is known as the "Land of the Free" --
Thanksgiving! Thanksgiving!

~Author Unknown

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